



GUIDANCE DOCUMENT FOR APPLICATION FOR LABORATORY REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT BIOLOGICAL AGENTS AND TOXINS

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 08/31/2003



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness Response Act of 2002" (Public Law 107-188) signed into law on June 12, 2002, requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select biological agents and toxins were published by HHS (42 CFR 73; December 13, 2002) and by USDA (9 CFR 121 and 7 CFR 331; December 13, 2002).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, HHS/CDC and the USDA/APHIS have developed a common reporting form for this data collection. This form is designed to assist entities or facilities in complying with this legal obligation.

This application package is for entities required to register to possess, use, or transfer select agents under Public Law 104-132 and its implementing regulation (42 CFR 73 - *Select Biological Agents and Toxins*; 7 CFR 331 - *Possession, Use, and Transfer of Biological Agents and Toxins*; and 9 CFR 121- *Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins*). An entity¹ is required by law (42 CFR 73.15, 9 CFR 121, and 7 CFR 331) to register with either CDC or APHIS if they wish to use, possess, or transfer select biological agents or toxins. The entity should assign a Responsible Official (RO) to assume responsibility for providing application information to the appropriate agency. The agency that the RO should contact is determined by the type of select biological agent or toxin that they possess. For HHS agents, the RO should contact CDC (telephone: 404-498-2255; facsimile 404-498-2265). For USDA agents, the RO should contact APHIS (for animal agents and toxins, telephone: 301-734-3277; facsimile: 301-734-3652). For HHS/USDA overlap agents, the RO should contact either APHIS or the CDC. For plant agents and toxins the RO should contact APHIS (telephone: 301-734-5519; facsimile: 301-734-8700). A listing of HHS select biological agents and toxins is available at <http://www.cdc.gov/od/sap>. A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The list of plant agents and toxins is available at <http://www.aphis.usda.gov/ppq/permits>.

RESPONSIBLE OFFICIAL

The regulation requires that a RO of the entity be identified, that the entity has facilities meeting the requirements to work safely with select agent(s), that only authorized personnel have access to select agents, and that registered entities keep records of select agents transferred to and from their facilities. The RO must be approved based on a security risk assessment by The Attorney General (Public Act 212(e)(3)), be familiar with the regulations (42 CFR 73, 7 CFR 331, and 9 CFR 121), and have the authority and responsibility to ensure that the requirements of the appropriate regulations are met.

An entity may also designate an alternate RO in cases where extended absences or other circumstances warrant acting for the RO in his or her absence. The alternate RO must meet all of the qualifications for a RO. We recommend that the RO and alternate RO are biosafety officers or senior management officials of the entity, or both. Although we understand that some entities have limited staff, we recommend that the RO not be an individual actually using, working with, or transferring or receiving the select agents and toxins to minimize potential conflicts of interest.

¹ Entity as defined by HHS/CDC means any government agency (Federal, State, or local), university, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity, including an individual acting on his or her own. Entity as defined by USDA/APHIS means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

The purpose of the RO and alternate RO is to ensure management oversight of the implementation of the select agent regulations and to provide an established point of contact for the entity. He or she is the designated individual responsible for all activities relating to the handling or transfer of select agents under the regulation. The RO and alternate RO must review and sign the Certification form (Section 2), and will be the person(s) contacted if CDC or APHIS have questions concerning the application or other matters related to the regulation. The RO or alternate RO should consult with others (e.g., engineering support services, principal investigators) as necessary to obtain the information required for this application. The RO or his or her alternate RO are also responsible for notifying CDC or APHIS of any changes to the registration, such as modifications to authorized laboratory personnel, changes in currently registered laboratories, additional new laboratories that require registration, or changes in protocols.

REGISTRATION

Entities wishing to register must submit an application to CDC or APHIS for review. Attachments to this application package include 42 CFR 73, 7 CFR 331, and 9 CFR 121. Before you complete this application please read these documents carefully to determine whether your entity is required to register. Note that there are some exemptions to the registration requirement (see 42 CFR 73.6). The RO should also perform a facility risk assessment that is based on the requirements for handling that agent to ensure that the facility meets those requirements. If information supplied in the application package indicates that the entity is properly equipped and capable of handling and transferring select agents, CDC or APHIS may issue a registration certificate to the entity. The registration is valid for a period up to three years. All entities will be subject to inspection during the three year registration period.

If an entity's application fails to document that the entity is properly equipped and capable of work with select agents, or if the application is incomplete, the entity will not be registered. CDC or APHIS will inform the entity of problems with the application by contacting the designated RO. Upon resolution of the problem, the entity may again seek registration. Allow at least 8 weeks for processing. Submission of an incomplete application will result in a significant delay in processing the application. Send all supporting documentation in black and white, not color.

Information on this application is not subject to the Freedom of Information Act (5 USC 552) under Public Law 107-188.

CONTENTS OF THIS APPLICATION PACKAGE

1. Application overview and instructions for registration of entity
2. Forms to be completed by applicants
3. Attachments (attachments include the regulation and several clarification documents. All applicants should review these before completing the application forms)
 - a. 42 CFR Part 73. *Select Biological Agents and Toxins*; Interim Final Rule. Federal Register, December 13, 2002.
 - b. 9 CFR Part 121 - *Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins*. Federal Register, December 13, 2002
 - c. 7 CFR 331 – *Possession of Select Agents*. Federal Register, December 13, 2002
 - d. Application for permit to: Import or transport controlled material or organisms or vectors (VS form 16-3)
 - e. Additional Information for cell cultures and their products (VS form 16-7)
 - f. Guidance document for report of transfer of select biological agents and toxins and EA-101

Please note that this application has been revised. This guidance document and form are also available at <http://www.cdc.gov/od/sap> or <http://www.aphis.usda.gov/vs/ncie/bta.html>.

INSTRUCTIONS FOR REGISTRATION OF ENTITY

Forms to be completed by all applicants

- (1) Section 1- Entity, RO, and alternate RO information.
- (2) Section 2 - Certification and Signature form. This form must be signed by the RO and the alternate RO for the institution.
- (3) Section 3 - Indicate each select agent or toxin which are currently in possession, use or in storage at the entity, or those that you anticipate working with in the near future (e.g., within 6 months).

(4) Section 4 - Laboratory and biosafety information summary for the entity (Section 4A) and information on personnel requiring access must be completed (Section 4B). For each of the select agents the entity plans to use, list the following information on a separate line: the select agent(s); the characteristics of each select agent (e.g., viable, genomic, recombinant material, use in small or large animals, or large scale), the building and room number(s) where select agent(s) will be used and stored, and, the facility risk assessment based on the requirements for the type of activities conducted in each of the rooms. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

Example 1. An entity needs to register one principal investigator (e.g., Dr. Jane Doe will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2; large scale production of *Bacillus anthracis* in Bldg A, Room 5 at BSL3; and *Bacillus anthracis* in small mammals in Bldg B, Room 200 at ABSL2). Storage of the agents will be in the same locations where the work will be conducted.

AGENTS/ACTIVITIES TO BE CONDUCTED AT THE FACILITY														
	Facility Agent ID	Viable	Genomic material	Recombinant DNA	Small Animal	Large Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level	Principal Investigator
									Bldg	Room	Bldg	Room		
SELECT AGENT	INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE													
Bacillus anthracis		X							A	2	A	2	BSL2	Dr. Jane Doe
Bacillus anthracis							X		A	5	A	5	BSL3	Dr. Jane Doe
Bacillus anthracis					X				B	200	B	200	ABSL2	Dr. Jane Doe

Example 2. An entity needs to register three principal investigators (e.g., Dr. John Smith will be working with recombinant Ebola in Bldg 15, Room 100 at NIHBSL-4; Dr. Mary Johnson will be working with botulinum toxins in Bldg 3A, Room 1000 under 29 CFR 1910.1450 conditions; and Dr. Tony Small will be working with viable *Francisella tularensis* in Bldg 4, Room 300 at BSL3 and viable *Brucella melitensis* in the same room). Storage of the agents will be in the same locations where the work will be conducted.

AGENTS/ACTIVITIES TO BE CONDUCTED AT THE FACILITY														
	Facility Agent ID	Viable	Genomic material	Recombinant DNA	Small Animal	Large Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level	Principal Investigator
									Bldg	Room	Bldg	Room		
SELECT AGENT	INDICATE WITH AN "X" FOR EACH AGENT AS APPROPRIATE													
Ebola virus				X					15	100	15	100	NIHBL4	Dr. John Smith
Botulinum toxin								X	3A	1000	3A	1000	29 CFR	Dr. Mary Johnson
Francisella tularensis		X							4	300	4	300	BSL3	Dr. Tony Small
Brucella melitensis		X							4	300	4	300	BSL3	Dr. Tony Small

*Biosafety Level 2=BSL2
Biosafety Level 3=BSL3
Biosafety Level 4=BSL4

Animal Biosafety Level 2=ABSL2
Animal Biosafety Level 3=ABSL3
Animal Biosafety Level 4=ABSL4

rDNA BSL2=NIHBL2
rDNA BSL3=NIHBL3
rDNA BSL4=NIHBL4

rDNA Large Animal BSL2=NIH BL2N
rDNA Large Animal BSL3=NIH BL3N
rDNA Large Animal BSL4=NIH BL4N

rDNA Large Scale BSL2=NIH BL2-LS
rDNA Large Scale BSL3=NIH BL3-LS
rDNA Large Scale BSL4=NIH BL4-LS

Toxin= 29 CFR 1910.1450, 29 CFR 1910.1200 and BMBL Appendix I

(5) Section 5A and 5B– All RO's should complete these sections for *each* of the principal investigators at their institution. Complete Sections 5C through 5G as appropriate for the agents in use.

FACILITY RISK ASSESSMENTS AND SAFETY LEVELS: REQUIREMENTS FOR HANDLING SELECT AGENTS

All entities using select agents should base their facility risk assessments on the applicable sections of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), *NIH Guidelines for Research Involving Recombinant DNA* (NIH Guidelines), 29 CFR 1910.1450, or other required assessment materials.

- Laboratories working with live select agent viruses, bacteria, or fungi should base their facility risk assessments on the BMBL. Use the BMBL to determine the appropriate Biosafety Level (BSL) for the various types of work to be conducted with each of the select agents you have listed in Section 5A.
- Laboratories working with recombinant DNA or genetic elements should base their facility assessment on the *NIH Guidelines* to determine the recommended Biosafety Level (BSL) for the type of work to be conducted with each of the select agents you have listed in Section 4. Institutions using recombinant DNA for large animal studies or in large scale production should base their facility risk assessments on the *NIH Guidelines*, as there are no corresponding sections in the BMBL.
- Laboratories working with select agent toxins should meet the requirements of 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*, and the toxin guidelines contained in Appendix I of the BMBL. If the entity is also working with intact select toxin-producing organisms or recombinant DNA encoding for select agent toxins, the laboratory should base its facility risk assessments on the BMBL and/or *NIH Guidelines* in addition to 29 CFR 1910.1450. Certain conditions may exclude select agent toxins from the requirements of this regulation (see 42 CFR 73.4(e)(1) and 42 CFR 73.5(e)(1)).
- Distributors of toxins in which the toxins are only handled in sealed containers should meet the requirements 29 CFR 1910.1200, *Hazard Communication*.

FOR HHS SELECT AGENTS, SEND COMPLETED FORMS TO CDC:

Centers for Disease Control and Prevention
Select Agent Program
1600 Clifton Road, NE
Mail Stop E-79
Atlanta, GA 30333

FOR USDA HIGH CONSEQUENCE AGENTS, SEND COMPLETED FORMS TO APHIS:

Animal and Plant Health Inspection Service
National Center for Import and Export
4700 River Road, Unit 40
Riverdale, MD 20737-1231

FOR HHS/USDA OVERLAP AGENTS, SEND COMPLETED FORMS TO:

Either CDC or APHIS at the addresses listed above

FOR PLANT AGENTS/TOXINS, SEND COMPLETED FORMS TO:

Biological and Technical Services
Plant Protection Quarantine
Animal and Plant Health Inspection Service
4700 River Road Unit 133
Riverdale, MD 20737-1236

ADDITIONAL MATERIALS YOU MAY NEED:

- (1) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). The BMBL is available on the internet at <http://www.cdc.gov/od/sap>. An errata sheet for the most current edition of the BMBL is available at the internet website: <http://www.cdc.gov/od/sap>.

- (2) *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)*, April 2002. The *NIH Guidelines* are available at <http://www.cdc.gov/od/sap> or contact CDC (phone 404-498-2255).
- (3) 29 CFR 1910.1450 - *Occupational Exposure to Hazardous Chemicals in the Laboratory*. Available on the Internet at <http://www.osha.gov/> or from the U.S. Government Printing Office (phone 202-512-1800).
- (4) 29 CFR 1200 - *Hazard Communication*. Available on the Internet at <http://www.osha.gov/> or from the U.S. Government Printing Office (phone 202-512-1800).
- (5) Additional information and clarification is available at <http://www.cdc.gov/od/sap>, <http://www.aphis.usda.gov/vs/ncie/bta.html>, and <http://www.aphis.usda.gov/ppq/permits>.

HOW TO AMEND YOUR REGISTRATION

To add, delete or change information on your registration, complete Sections 1 through 5A, and Sections 5B through 5G and return to the appropriate agency. These forms are available on the internet at <http://www.cdc.gov/od/sap>, <http://www.aphis.usda.gov/vs/ncie/bta.html> and <http://www.aphis.usda.gov/ppq/permits>.

HOW TO DESIGNATE A DIFFERENT OR ALTERNATE RO

To designate a different RO or an alternate RO, the current RO must mail or fax to the appropriate agency a signed statement on official entity facility letterhead requesting such changes. In addition, the new RO or alternate RO must submit Sections 1 and 2. The alternate RO must meet all of the qualifications for a RO. See additional details outlined in the section above entitled *Responsible Official*.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact CDC at (404) 498-2255 or APHIS at (301) 734-3277. It is also permissible to photocopy the originals contained in this application package if additional copies are needed. This application and guidance document is also available on the CDC Web site at <http://www.cdc.gov>, <http://www.aphis.usda.gov/vs/ncie/bta.html> and <http://www.aphis.usda.gov/ppq/permits>.

HOW THE INFORMATION IN THIS APPLICATION PACKAGE WILL BE USED

Each section of the application package is designed to obtain specific information required under 42 CFR 73, 7 CFR 331, and 9 CFR 121.

PUBLIC REPORTING BURDEN

The public reporting burden of this collection of information for the requirements of this application request is estimated to be 225 minutes. An agency may not conduct, nor is an individual required to respond to, information collection unless a current valid OMB control number has been issued. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, ATTN: PRA (0920-0576), MS D-24, Atlanta, Georgia 30333.



**APPLICATION FOR LABORATORY REGISTRATION FOR
POSSESSION, USE, AND TRANSFER OF SELECT
BIOLOGICAL AGENTS AND TOXINS**

FORM APPROVED
OMB NO. 0579-0213
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EXP DATE 08/31/2003



Read all instructions carefully before completing the application. Answer all items completely and type or print in ink. All documentation must be in black and white, not color. The application must be signed or it will not be processed. For HHS agents, submit document to: Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333. For USDA animal agents, submit document to: National Center for Import and Export, VS, APHIS, 4700 River Road Unit 40, Riverdale, MD 20737-1231. For HHS/USDA overlap agents submit the form to either CDC or APHIS. For USDA plant agents and toxins, return completed forms to: Biological and Technical Services, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737-1236.

SECTION 1 – ENTITY INFORMATION (TO BE COMPLETED BY ALL RO'S)				
Before completing the application, read all instructions carefully. Give complete answers to all items. Type or print in ink.				
This application is: <input type="checkbox"/> A new registration <input type="checkbox"/> A renewal of an existing registration <input type="checkbox"/> An amendment to an existing registration				
Current entity registration number (if applying for amendment or renewal) APHIS# _____ CDC# _____			Date _____	
Legal name of entity _____				
Address (NOT a post office box) _____		City _____	State _____	Zip Code _____
Type of entity: <input type="checkbox"/> Academic <input type="checkbox"/> Government <input type="checkbox"/> Commercial <input type="checkbox"/> Private <input type="checkbox"/> Other (please explain): _____				
Name of Responsible Official (RO) _____		Date of birth _____	Title of Responsible Official (e.g., biosafety officer) _____	
Telephone _____		FAX _____	E-mail _____	
Address (NOT a post office box) _____		City _____	State _____	Zip Code _____
Name of alternate Responsible Official _____		Date of birth _____	Title of alternate Responsible Official _____	
Telephone _____		FAX _____	E-mail _____	
Address (NOT a post office box) _____		City _____	State _____	Zip Code _____
Has this laboratory previously been registered with the CDC Select Agent Program under 42 CFR 72.6? Yes No If yes, then provide CDC Select Agent Transfer Program registration number and expiration date: _____				
Has this laboratory previously been registered with the USDA High Consequence Agent Program? Yes No If yes, then provide USDA High Consequence Agent Program registration number and expiration date: _____				

SECTION 2 – CERTIFICATION AND SIGNATURE
(TO BE COMPLETED BY ALL RO'S AND ALTERNATE RO'S)

I hereby certify that I have been designated as the Responsible Official or the Alternate Responsible Official for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied in this registration package is, to the best of my knowledge, accurate and truthful. The institution/organization listed above meets the requirements specified in 42 CFR 73, 9 CFR 121, and 7 CFR 331 is equipped and capable of safely handling the agent(s) and will use or transfer these agents solely for purposes authorized by 42 CFR 73, 9 CFR 121, and 7 CFR 331.

I understand that a false statement on any part of this agreement or failure to comply with the provisions of the applicable regulations may result in the immediate revocation of this facility's registration as described in 42 CFR 73, 9 CFR 121, and 7 CFR 331 and could result in a civil fine of up to \$500,000 for each violation, or if criminally prosecuted a criminal fine or imprisonment for up to five years, or both for each violation. (7 U.S.C. 8401; 18 U.S.C. 175, 175b, 1001, 3559, 3571; 42 U.S.C. 264, 271).

Responsible Official Signature	Date	RO Name (typed or printed)
Alternate Responsible Official Signature	Date	Alternate RO Name (typed or printed)

Date: _____

SECTION 3 – SELECT AGENTS USED, POSSESSED, OR TRANSFERRED BY ENTITY
(TO BE COMPLETED BY ALL RO'S)

Indicate each select agent or toxin in use or storage at your facility by placing an "X" in the box for each agent or toxin possessed by your facility (check one or more categories as appropriate). Items that are exempt from registration should not be listed on this form.

HHS NON-OVERLAP SELECT AGENTS AND TOXINS

- ☐ Crimean-Congo haemorrhagic fever virus
- ☐ *Coccidioides posadasii*
- ☐ Ebola viruses
- ☐ Cercopithecine herpesvirus 1 (Herpes B virus)
- ☐ Lassa fever virus
- ☐ Marburg virus
- ☐ Monkeypox virus
- ☐ *Rickettsia prowazekii*
- ☐ *Rickettsia rickettsii*
- South American haemorrhagic fever viruses
 - ☐ Junin
 - ☐ Machupo
 - ☐ Sabia
 - ☐ Flexal
 - ☐ Guanarito
- Tick-borne encephalitis complex (flavi) viruses
 - ☐ Central European tick-borne encephalitis
 - ☐ Far Eastern tick-borne encephalitis
 - ☐ Russian spring and summer encephalitis
 - ☐ Kyasanur forest disease
 - ☐ Omsk hemorrhagic fever
- ☐ Variola major virus (Smallpox virus)
- ☐ Variola minor virus (Alastrim)
- ☐ *Yersinia pestis*
- ☐ Abrin
- ☐ Conotoxins
- ☐ Diacetoxyscirpenol
- ☐ Ricin
- ☐ Saxitoxin
- ☐ Shiga-like ribosome inactivating proteins
- ☐ Tetrodotoxin

HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS/ SELECT AGENTS (OVERLAP AGENTS)

- ☐ *Bacillus anthracis*
- ☐ *Brucella abortus*
- ☐ *Brucella melitensis*
- ☐ *Brucella suis*
- ☐ *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- ☐ *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- ☐ Botulinum neurotoxin producing species of *Clostridium*
- ☐ *Coccidioides immitis*
- ☐ *Coxiella burnetii*
- ☐ Eastern equine encephalitis virus
- ☐ Hendra virus
- ☐ *Francisella tularensis*
- ☐ Nipah Virus
- ☐ Rift Valley fever virus
- ☐ Venezuelan equine encephalitis virus
- ☐ Botulinum neurotoxin
- ☐ *Clostridium perfringens* epsilon toxin
- ☐ Shigatoxin
- ☐ Staphylococcal enterotoxin
- ☐ T-2 toxin

USDA HIGH CONSEQUENCE LIVESTOCK PATHOGENS AND TOXINS (NON-OVERLAP AGENTS AND TOXINS)

- ☐ Akabane virus
- ☐ African swine fever virus
- ☐ African horse sickness virus
- ☐ Avian influenza virus (highly pathogenic)
- ☐ Blue tongue virus (Exotic)
- ☐ Bovine spongiform encephalopathy agent
- ☐ Camel pox virus
- ☐ Classical swine fever virus
- ☐ *Cowdria ruminantium* (Heartwater)
- ☐ Foot and mouth disease virus
- ☐ Goat pox virus
- ☐ Lumpy skin disease virus
- ☐ Japanese encephalitis virus
- ☐ Malignant catarrhal fever virus (Exotic)
- ☐ Menangle virus
- ☐ *Mycoplasma capricolum*/M.F38/*M. mycoides capri*
- ☐ *Mycoplasma mycoides mycoides*
- ☐ Newcastle disease virus (VVND)
- ☐ Peste Des Petits Ruminants virus
- ☐ Rinderpest virus
- ☐ Sheep pox virus
- ☐ Swine vesicular disease virus
- ☐ Vesicular stomatitis virus (Exotic)

LISTED PLANT PATHOGENS

- ☐ *Liberobacter africanus*
- ☐ *Liberobacter asiaticus*
- ☐ *Peronosclerospora philippinensis*
- ☐ *Phakopsora pachyrhizi*
- ☐ Plum Pox Potyvirus
- ☐ *Ralstonia solanacearum* race 3, biovar 2
- ☐ *Schlerophthora rayssiae* var *zeae*
- ☐ *Synchytrium endobioticum*
- ☐ *Xanthomonas oryzae*
- ☐ *Xylella fastidiosa* (citrus variegated chlorosis strain)

Date: _____

SECTION 4 – SELECT AGENT INFORMATION (TO BE COMPLETED BY ALL RO'S)

SECTION 4A. BIOSAFETY AND LABORATORY INFORMATION ON SELECT AGENTS

All applicants must complete this table. Each select agent used at different risk levels should be listed separately for each laboratory. Failure to complete this table in detail will delay processing of your application. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

[illegible]

*Biosafety Level 2=BSL2
Biosafety Level 3=BSL3
Biosafety Level 4=BSL4

Animal Biosafety Level 2=ABSL2
Animal Biosafety Level 3=ABSL3
Animal Biosafety Level 4=ABSL4

rDNA BSL2=NIHBL2
rDNA BSL3=NIHBL3
rDNA BSL4=NIHBL4

rDNA Large Animal BSL2=NIH BL2N
rDNA Large Animal BSL3=NIH BL3N
rDNA Large Animal BSL4=NIH BL4N

rDNA Large Scale BSL2=NIH BL2-LS
rDNA Large Scale BSL3=NIH BL3-LS
rDNA Large Scale BSL4=NIH BL4-LS

Toxin= 29 CFR 1910.1450, 29 CFR 1910.1200 and BMBL Appendix I

Registration number (if applicable) _____

SECTION 4B – AUTHORIZED PERSONNEL WORKING WITH SELECT AGENTS

Provide the following information for the RO, alternate RO, owners of the entity, as well as *each* person who is authorized to have access to select agents in the institution. The information provided in this section must correspond to that presented in Section 3 and 4A or it will delay processing the application. To request additions to or deletions from this list of individuals, submit this page to the same agency that you filed your original application with (CDC or APHIS). The first and last name of each individual should correspond exactly to the information submitted to the Attorney General.

Last Name	First Name	Middle Initial	Date of Birth	Home Address (No P.O. boxes)	Supervising Principal Investigator (PI's, RO's, and owners leave this column blank)	Agent(s)/Toxins	Laboratory Building	Laboratory Room	Job Title

*SRA=security risk assessment

I certify that the individuals listed above have a legitimate need for access to select agents in the laboratories listed above, and that each individual has the training and skills to safely work with these agents or toxins.

RO Signature: _____ Date: _____

Laboratory supervisor: _____ Laboratory building: _____ Laboratory room number(s): _____ Date: _____

SECTION 5 – LABORATORY INFORMATION
(COMPLETED BY EACH LABORATORY SUPERVISOR AND APPROVED BY THE RO)

Provide the following information for each laboratory working with select agents at the institution. Make additional copies of this section of the form as needed for each principal investigator at your facility. Each laboratory supervisor should complete questions 3 through 46, as appropriate for *each* laboratory room where select agents are used or stored. Incomplete answers will delay processing the application. In the "facility agent ID" column indicate any identification used to identify a specific agent or toxin or derivatives of these (i.e., EEE-p102 to identify a modified strain of EEE that is unique to your laboratory).

SECTION 5A – TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR

Include a current resume or Curriculum Vitae from the principal investigator.

1. Name of individual responsible for the laboratory (e.g., principal investigator or laboratory supervisor): _____
2. Provide the following information for each agent(s) worked with or stored in the laboratory building(s) and room(s) specified in section 4B:

AGENT/TOXIN NAME	STRAIN DESIGNATION	DATE ACQUIRED	ADDRESS OF FACILITY FROM WHICH THE AGENT/TOXIN WAS ACQUIRED (Include registration number if applicable)	FACILITY AGENT I.D.	SOURCE OF ISOLATE			UNIQUE DIAGNOSTIC CHARACTERISTICS	REFERENCE FOR PUBLISHED SEQUENCE INFORMATION (GenBank accession number, journal articles, etc.)	HOST RANGE (i.e. man and birds)
					Clinical	Environmental	Other (explain)			

SECTION 5A – TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR (Continued)

Make additional copies of this section of the form as needed for *each* laboratory room for each laboratory supervisor at your facility. Each laboratory supervisor should complete questions 3 through 46, as appropriate for *each* laboratory where select agents are used or stored. If all laboratories with the same biosafety level under the control of one laboratory supervisor meet the same criteria, then list all laboratory rooms and submit only one form. Include a floor plan for each laboratory where agents or toxins are to be used or stored (for all biosafety levels).

3. Floor plan(s) include:

- a. Sink locations ☐ Yes ☐ No
- b. Eyewash locations ☐ Yes ☐ No
- c. Biosafety cabinet (BSC) locations ☐ Yes ☐ No
- d. Fume hood locations ☐ Yes ☐ No
- e. HVAC supply and exhaust locations ☐ Yes ☐ No
- f. Freezer/refrigerator locations ☐ Yes ☐ No
- g. Other large equipment locations (incubators, centrifuges, etc) ☐ Yes ☐ No

4. Provide a description of the HVAC system (*check all that are appropriate*):

- a. ☐ Single-pass ☐ Re-circulated
- b. ☐ Dedicated exhaust ☐ Shared exhaust
- c. ☐ Constant air volume ☐ Variable air volume
- d. ☐ Redundant exhaust fans
- e. ☐ Emergency power back-up

5. Provide information on the biosafety cabinets in use (attach additional sheets if needed):

- a. Class of cabinet: ☐ I ☐ II, Type A1 ☐ II, Type A2 (formerly II, B3) ☐ II, B1 ☐ II, B2 ☐ III
- b. Biosafety cabinet connection to the HVAC system: ☐ Hard duct ☐ Thimble ☐ Re-circulating
- c. Define certification period: ☐ Annual ☐ Biannual ☐ Other (explain): _____
- d. Does user verify air inflow during BSC use? ☐ Yes ☐ No

6. **NOTE:** BSL-4 or ABSL-4 laboratories are very specialized facilities. Please contact the CDC office for specific guidance for registering a BSL-4 or ABSL-4 laboratory.

7. BSL-3 laboratory registration must answer the following:

- a. Entry into the lab is through a double set of lockable self-closing doors: ☐ Yes ☐ No
- b. Each laboratory room has a hands-free sink: ☐ Yes ☐ No
- c. An eyewash station is readily available inside the laboratory: ☐ Yes ☐ No
- d. There is an autoclave or other verified or approved method for decontamination within the laboratory: ☐ Yes ☐ No
- e. If no autoclave in the BSL-3 laboratory, describe waste handling protocols to be used by the laboratory personnel:

- f. Laboratory exhaust is re-circulated to other areas of the facility: ☐ Yes ☐ No
- g. The laboratory is maintained at negative air pressure to provide directional air into the laboratory: ☐ Yes ☐ No
- h. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the laboratory: ☐ Yes ☐ No
- i. An alarm system is provided to warn laboratory personnel of exhaust system failure: ☐ Yes ☐ No
- j. HEPA filtration of all exhaust air is in place: ☐ Yes ☐ No

8. ABSL-2 laboratory registration must answer the following:

- | | | |
|--|------------------------------|-----------------------------|
| a. Animal laboratories are separated from open and unrestricted areas: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Animal laboratory exhaust is re-circulated to other areas of the facility: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. There is an autoclave in the laboratory: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. External doors are self-closing, self-locking, and open inward: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. Cage washing is: <input type="checkbox"/> Manual <input type="checkbox"/> With a mechanical cage washer | | |
| g. The cage washing area is shown on attached floor plan: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. Each animal room where infected animals are kept contains a hand-washing sink: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| i. If floor drains are provided, the traps are always filled with an appropriate disinfectant: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

9. ABSL-3 laboratory registration must include the following:

- | | | |
|--|------------------------------|-----------------------------|
| a. Animal laboratories are separated from open and unrestricted areas: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| b. Entry into the animal lab is through a double set of lockable self-closing doors: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| c. External doors are self-closing, self-locking, and open inward: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| d. Each animal room contains a hands-free hand washing sink: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| e. Animal laboratory exhaust is re-circulated to other areas of the facility: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| f. The animal laboratory is maintained at negative air pressure to provide directional air into the animal laboratory: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| g. A visual system is provided for laboratory personnel to monitor directional air before entry and during use of the animal laboratory: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| h. An alarm system is provided to warn laboratory personnel of exhaust system failure: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| i. HEPA filtration of all exhaust air is present: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| j. There is an autoclave in the laboratory: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| k. Cage washing is with a mechanical cage washer: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| l. Cage washing area is shown on the floor plans: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| m. Animal waste treated (carcasses, sewage, bedding, etc.) before disposal | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| If yes describe treatment method: _____ | | |
| n. If floor drains are provided, the traps are always filled with an appropriate disinfectant: | <input type="checkbox"/> Yes | <input type="checkbox"/> No |

10. Appropriate personal protective equipment is used: ☐ Yes ☐ No

11. Vacuum lines contain HEPA filters: Yes No No vacuum lines are used

12. Each laboratory using select agents has an agent-specific, site-specific biosafety manual: ☐ Yes ☐ No

13. A medical surveillance system is in place for laboratory personnel using select agents: ☐ Yes ☐ No

14. Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory director: ☐ Yes ☐ No

15. A sharps policy is in place for this laboratory (or laboratories): ☐ Yes ☐ No

16. A site-specific emergency operations plan is available for this laboratory: ☐ Yes ☐ No

17. An Institutional Biosafety Committee (IBC) reviews and approves protocols prior to work with select agents at this facility? ☐ Yes ☐ No ☐ Application submitted, but pending

a. If yes, has IBC approved the work proposed in this application: Yes ☐ No ☐

b. The facility has been inspected by USDA, FDA, CLIA, DoE, DoD or others: Yes ☐ No ☐

c. If yes, then give agency and date of last inspection(s): _____

18. Briefly state (no more than a paragraph) the objectives of the work with the select agent(s), including a description of the methodologies or laboratory procedures that will be used. State if any host-vector systems will be used. Specify whether work will involve live agents and recombinant DNA:

**SECTION 5B – TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR
(TRAINING AND SECURITY)**

19. Training:

- a. Site specific security and safety training is provided to individuals with access to areas where select agents are handled or stored: ☐ Yes ☐ No
- b. Is provided prior to individuals beginning to work with select agents: ☐ Yes ☐ No
- c. Is provided: ☐ Annually ☐ Biannually ☐ Other (specify frequency): _____
- d. Written records of individuals trained are kept: ☐ Yes ☐ No
- e. Personnel demonstrate proficiency in laboratory procedures prior to working with select agents: ☐ Yes ☐ No
- f. Provide a brief description of what is included in the training program:

20. Provide a brief explanation of the system in place to detect loss or theft of select agent(s):

- a. Individual responsible for inventory of select agent(s):

- b. How often is the inventory record reconciled?

- c. How is access to the inventory log limited?

- d. Inventory tracking includes the following information (list):

21. There is a site-specific security plan for each of the laboratories listed above in Section 5A (number 2): ☐ Yes ☐ No

- a. Building with select agents has self-closing doors: ☐ Yes ☐ No
- b. Means to limit access to buildings with laboratories with select agents:
- ☐ Guard station at the facility entrance
 - ☐ Card access system or locks
 - ☐ Security alarm system in the laboratory building
 - ☐ Other (describe): _____
-
- c. Means to limit access to laboratories with select agents once inside the building:
- ☐ Door to laboratory is locked

- ☐ Guard station at the building entrance
- ☐ Card access system or locks
- ☐ Security alarm system in the laboratory
- ☐ Other (describe): _____
- d. Means to limit access to select agents once inside the laboratory:
 - ☐ Locked incubators, refrigerators, freezers, etc.
 - ☐ Security alarm system that directly monitors the laboratory
 - ☐ Other (describe): _____
- e. Means to limit access to select agents in storage:
 - ☐ Storage area door locked
 - ☐ Lock boxes
 - ☐ Security alarm system that directly monitors the laboratory
 - ☐ Other (describe): _____
- f. Means to monitor unauthorized entry into the laboratory where select agents are used or stored:
 - ☐ Electronic logs of card access system entries are reviewed for unusual activity
 - ☐ Manual sign in and out logs are kept and monitored
 - ☐ Video camera surveillance
 - ☐ Other (describe): _____
- g. The laboratory is secured when no one is present during regular working hours: ☐ Yes ☐ No
- h. Number of people with access: _____
- i. Individuals not directly involved in research activities have access to select agents: ☐ Yes ☐ No
If yes, please explain: _____
- j. Non-laboratory personnel (visitors, including janitorial and facility maintenance personnel) have access to the laboratory with select agents: ☐ Yes ☐ No
If yes, are they allowed into the laboratory unescorted? ☐ Yes ☐ No
- k. Provide additional details regarding how the facility limits access to the laboratories where select agents are being manipulated and stored to only authorized and qualified persons:

**SECTION 5C –TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR
WORKING WITH INFECTIOUS AGENTS**

22. Provide an estimate of the maximum quantities (e.g., number of petri dishes or flasks) and concentration of organisms grown at a given time: _____
23. All cultures, stock and other regulated wastes are decontaminated before disposal by an approved decontamination method: ☐ Yes ☐ No
- a. If yes, describe method: _____

**SECTION 5D – TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR
WORKING WITH RECOMBINANT DNA**

24. The facility has an Institutional Biosafety Committee that has approved work with recombinant DNA or has approval pending: ☐ Yes ☐ No
25. The biosafety level listed in Section 4A for this laboratory meets NIH guidelines: ☐ Yes ☐ No
26. Will you be possessing, using or transferring the following:
- a. Select agent viral nucleic acids (synthetic or naturally derived, contiguous or fragmented, in host chromosomes or in expression vectors) that are capable of infection and/or replication. ☐ Yes ☐ No

- b. Nucleic acids (synthetic or naturally derived) that encode for the functional form(s) of any of the toxins listed in paragraph (d) of this section if the nucleic acids are in a vector or host chromosome and/or are expressed *in vivo* or *in vitro*. ☐ Yes ☐ No
- c. Select agent viruses, bacteria, fungi, and toxins that have been genetically modified. ☐ Yes ☐ No

27. Are you intending to conduct the following experiments:

- a. Experiments utilizing recombinant DNA techniques that involve the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. ☐ Yes ☐ No
- b. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxin molecules lethal for vertebrates at an LD₅₀ < 100 ng/kg body weight. ☐ Yes ☐ No

28. Provide a brief description of the recombinant constructs and any associated expression control elements, including what the recombinant DNA encodes for, if known: _____

29. Give an estimate of range of length of recombinant DNA to be used: _____

SECTION 5E – TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH SMALL ANIMALS

30. List species of small animals that will be used: _____

31. Describe route of infection: _____

32. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

a. If yes, describe method: _____

33. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility: ☐ Yes ☐ No

a. If yes, the proposed work with select agents in small animals has been approved by the IACUC: ☐ Yes ☐ No

34. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

a. If yes, give inspection date: _____

SECTION 5F – TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH LARGE ANIMALS

35. List species of large animals that will be used: _____

36. Describe route of infection: _____

37. Carcass of animals are disposed of to avoid their use as food for human beings or animals: ☐ Yes ☐ No

38. Animal waste is treated prior to disposal (e.g., carcasses, sewage, bedding, etc.): ☐ Yes ☐ No

a. If yes, give method: _____

39. Carcass of animals are disposed of on site: ☐ Yes ☐ No

40. The facility requires that an Institutional Animal Care and Use Committee (IACUC) review and approve protocols prior to work with animals at this facility: ☐ Yes ☐ No

a. If yes, the proposed work with select agents in small animals has been approved by the IACUC: ☐ Yes ☐ No

41. The laboratory space is accredited by AAALAC: ☐ Yes ☐ No

a. If yes, give inspection date: _____

SECTION 5G – TO BE COMPLETED BY ALL ENTITIES FOR EACH LABORATORY SUPERVISOR WORKING WITH TOXINS

42. A Chemical hygiene plan is available for the facility using toxins: ☐ Yes ☐ No

43. Maximum quantity of each toxin under the control of the principal investigator at a given time: _____

44. Form of toxins used: ☐ Liquid ☐ Lyophilized

45. The toxin is produced by live agent at the facility: ☐ Yes ☐ No
- a. If yes, provide a brief description of procedures used (include an estimate of the maximum quantities grown at a given time): _____
46. Dilution procedures and other manipulations of the concentrated toxins are:
- a. Conducted in ☐ Fume hood ☐ Biosafety cabinet
- 1) If a fume hood is used, certification of the hood is conducted:
☐ Annually ☐ Biannually ☐ Other (describe): _____
- b. Conducted with two knowledgeable people present: ☐ Yes ☐ No
- c. A hazard sign on the door when toxins are present: ☐ Yes ☐ No

Attachments

Attachment 1. 42 CFR Part 73. Select Biological Agents and Toxins; Final Rule. Federal Register, December 13, 2002.

Attachment 2. 9 CFR Part 121 - Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins. Federal Register, December 13, 2002.

Attachment 3. 7 CFR 331 – Possession of Select Agents. Federal Register, December 13, 2002.

Attachment 4. APHIS application for permit to import or transport controlled material or organisms or vectors (VS form 16-3).

Attachment 5. Additional Information for cell cultures and their products (VS form 16-7).

Attachment 6. Guidance document for report of transfer of select biological agents and toxins and EA-101

The purpose of the CDC EA-101 form is to provide a method for the documentation of the transfer of a select agent. An EA-101 form must be completed for each transfer of a select agent. A copy of each EA-101 must be kept by the responsible official (RO) for three years.

Prior to transferring a select agent

Before a select agent is transferred, both the sender (transferor) and recipient (requestor) facilities must be registered with the CDC or APHIS. The agency that the Responsible Official (RO) should contact is determined by the type of select biological agent or toxin involved in the transfer. For HHS agents, the RO should contact CDC by facsimile (404-498-2265). For USDA agents, the RO should contact APHIS (for animal agents and toxins, telephone: 301-734-3277; facsimile: 301-734-3652). For HHS/USDA overlap agents, the RO should contact either APHIS or CDC. For plant agents and toxins the RO should contact APHIS (telephone: 301-734-5519; facsimile: 301-734-8700). A listing of HHS select biological agents and toxins is available at <http://www.cdc.gov/od/sap>. A listing of USDA animal agents and toxins is available at <http://www.aphis.usda.gov/vs/ncie/bta.html>. The list of plant agents and toxins is available at <http://www.aphis.usda.gov/ppq/permits>.

The recipient fills out blocks 1 and 2 of the EA-101 form and submits it to the sender. The sender's responsible official (RO) must FAX the form to CDC (FAX: 404-498-2265) or APHIS (FAX: 301-734-3652) to verify that the requesting facility: (1) retains a valid, current registration for the select agent being requested; (2) the person requesting the select agent is an employee of the requesting facility, and has been given Department of Justice clearance as an authorized individual to receive the select agent material to be transferred; and, (3) that the proposed use of the agent by the recipient is correctly indicated on CDC Form EA-101. CDC or APHIS will FAX back the form with a confirmation if the transfer information is approved. If the sender has a suspicion that the agent may not be used for the requested purpose, or there are any other concerns, then the sender should consult with the CDC.

Transfer:

(a) Shipment of the select agent to the recipient

The sender should ship the material to the receiver only after the sender has received a verification number from CDC or APHIS regarding the information in blocks 1 and 2 of the EA-101. The sender fills out Section 4, including the date the agent was shipped. Select agents must be packaged, labeled, and shipped in accordance with all federal regulations (e.g., 42 CFR 72, and 49 CFR 100-180) and international (IATA) regulations. It is highly recommended that the sender utilize a method for tracking the movement of the select agents being shipped. Return receipt is required by law for some select agents listed in 42 CFR part 72¹.

(b) Transmittal of the EA-101 form to the CDC or APHIS

The RO from the recipient's facility must fill out Section 4 of the EA-101 form with the date received and FAX the form back to both the Sender's RO and the CDC or APHIS. The recipient is required to provide a completed paper copy or facsimile transmission of the EA-101 form within 2 business days to the Sender RO and the CDC or APHIS.

Destruction or depletion of a select agent

When a select agent from a transfer is depleted or destroyed, the RO of the facility must complete the appropriate information in Block 4 of the Form. A copy or FAX of the EA-101 form must be sent to the CDC or APHIS.

¹*Coccidioides immitis*; Ebola virus; *Francisella tularensis*; Viruses causing HPS; CCHF; Junin Virus; Machupo virus; Lassa virus; Marburg virus; *Burkholderia mallei*; *Burkholderia pseudomallei*; Tick-borne encephalitis virus complex; Variola major virus; *Yersinia pestis*

Steps in transferring a select agent

Recipient RO	Sender RO
1. Completes agent description (Block 1)	
2. Completes recipient information (Block 2)	
3. Faxes form EA-101 and registration certificate to sender	
	4. Completes sender information (Block 3)
	5. Faxes form EA-101 to CDC or APHIS for verification number
	6. After receipt of approval by CDC or APHIS, sender completes shipping information (Block 4), except for date received
	7. Oversees packaging and shipment of agent to recipient. Sends shipment.
8. Receives agent	
9. Recipient RO completes Block 4 (i.e., date select agent material received and confirms that what was listed on packing inventory has been received) and provides paper copy or faxes form EA-101 to both CDC or APHIS and the sender within 2 business days of receipt.	
10. Retains paper record for 3 yr, or retains record 3 yr after agent consumed or destroyed, whichever is longer	10. Retains paper record for 3 yr, or retains record 3 yr after agent consumed or destroyed, whichever is longer